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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,311	11/29/2000	William D. Huse	P-IX 4526	3119

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EXAMINER
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DAVIS, KATHARINE F

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/727,311

Applicant(s)

HUSE, WILLIAM D.

Examiner

Katharine F. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 88-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 88-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This Office Action is in response to the application (with Preliminary Amendment) filed November 29, 2000. Claims 2-87 have been cancelled. New claims 88-91 have been added. Claims 1 and 88-91 are pending in the instant application.

#### ***Drawings***

The formal drawings filed on April 23, 2001 have been approved by the draftsman.

#### ***Specification***

The disclosure is objected to because of the following informalities: There are typographical errors at page 29, line 22 and at page 57, line 2. Appropriate correction is required.

In the Brief Description of the Drawings section each panel or drawing containing multiple panels must be referred to as a separate figure. The first line of each description must refer to each separate figure, for example page 4, line 4, "Figure 3" should read "Figures 3A-3E". Correction is required for Figures 3 and 5-10.

#### ***Claim Objections***

Claims 89 and 90 are objected to because of the following informalities: Claim 89 depends from itself. It is assumed for examination purposes that claim 89 depends from claim 88. Claim 90 does not end with proper punctuation. Appropriate correction is required for claims 89 and 90.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 recites the phrase "...processed fusion protein of claim 89..." There is insufficient antecedent basis for this phrase in the claim. Amending the claim to recite "...processed **gVIII** fusion protein of claim 89..." would overcome this rejection.

Claim 91 recites the phrase "...or modification thereof." It is unclear what modifications to the VIII gene are included within the scope of the claim, therefore the metes and bounds are undetermined and thereby indefinite. Furthermore, it is unclear what modifications can be made to the VIII gene that allow the function of the polypeptide product to be retained.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 88-91 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent

5,223,409 (Ladner *et al.*, IDS reference). Ladner *et al.* teaches processed gVIII fusion proteins and filamentous bacteriophages comprising said gVIII fusion proteins. The processed gVIII fusion proteins of Ladner *et al.* comprise a bovine pancreatic trypsin inhibitor-VIII fusion, said fusion comprising a functional portion of the gVIII protein of a filamentous bacteriophage which causes expression of said processed gVIII fusion protein on the surface of said filamentous bacteriophage from an infected compatible host cell (see columns 55-57, especially column 56-57 lines 67-7 and Example I). Ladner *et al.* also teaches (by noting the results of another researcher) that gene VIII can be mutated resulting in a gene VIII with a nucleotide sequence that is non-identical to the wild-type VIII nucleotide sequence (see column 55, lines 22-27). The claimed processed gVIII fusion proteins and filamentous bacteriophages read on those taught by Ladner *et al.*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 29 of U.S. Patent No. 6,258,530. Although the conflicting claims are not identical, they are not patentably distinct from one another. Claim 1 is drawn to a composition of matter comprising a plurality of cells containing a diverse population of expressible oligonucleotides. Claim 29 of the '530 patent is drawn to a composition of matter comprising a diverse population of oligonucleotides. It is clear from reviewing the instant specification and other claims of the '530 patent (*e.g.* claim 1) drawn to similar compositions of oligonucleotides (claims 18, 64 and 65) that the invention intends for the population of oligonucleotides to be contained within cells. It is known in the art that such compositions of oligonucleotides are experimentally usable when each oligonucleotide of the diverse population is contained within a cell. One of skill in the art would be motivated to place the diverse population of expressible oligonucleotides within cells for efficient experimental use. Thus, it is considered to be obvious to place each oligonucleotide in the composition of

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oligonucleotides claimed in claim 29 of the '530 into a cell to comprise a composition of matter comprising a plurality of cells containing a diverse population of expressible oligonucleotides. Therefore, claim 1 of the instant application and claim 29 of the '530 patent are not patentably distinct from one another.

***Conclusion***

Claims 1 and 88-91 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry of a general nature or any inquiry concerning the formalities of this application should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis  
February 10, 2002

DAVID GUZO  
PRIMARY EXAMINER  
